

### REMARKS

This is in response to the Office Action mailed April 17, 2008, in which the Examiner rejected claims 243-248, and 254-272.

#### Amendments

In the Office Action, the Examiner indicated the allowance of independent claims 249 and 273. Applicant has canceled claims 243-248 and 254-272 to place the application in condition for allowance.

Additionally, Applicant has added new claims 275-285, which depend from allowed independent claim 273. No additional search is required with regard to the new claims, because each of the new claims further narrows the independent claim from which they depend.

Entry of the amendments and allowance of the application, as amended, is respectfully requested.

#### Claim Rejections – 35 U.S.C. §103

In Section 2 of the Office Action, the Examiner rejected claims 243-248, and 254-272 under 35 U.S.C. §103(a) as being unpatentable over Suda et al. (U.S. Patent No. 5,978,712) in view of Barreras (U.S. Patent No. 5,807,397). Applicant has canceled each of the rejected claims to place the application in condition for allowance thereby rendering the rejections moot. However, the amendment should not be construed as acquiescence to any of the Examiner's findings with regard to claimed embodiments of the invention.

For example, previously presented claims 243, 244, 260, 261, 262, 271 and 272 each recite limitations with regard to the electrical waveform, such as describing the waveform as comprising "a range of pulse width durations that includes 2 ms" (claim 243). Although these limitations are not specifically taught by Suda et al., the Examiner found Suda et al. to teach "that many parameters including pulse width are 'arbitrarily set by the doctor or health worker in

accordance with the state of urinary incontinence.” (Citing page 4, lines 17-28 of Suda et al.).

Based on this finding, the Examiner concluded that:

a modification of the device [to] set the parameters to any needed level would have been obvious to one skilled in the art depending on the individual and particular state of incontinence. Clearly Suda et al. teaches that it would have been obvious to allow the device to be set to different parameters and the device is also used to treat urinary incontinence using electrodes implanted in the pelvic muscle, therefore to find the optimum workable ranges by routine experimentation would have been obvious to one skilled in the art as discussed above.

Applicant respectfully believes that this finding cannot support a *prima facie* case of obviousness against the claims.

The Examiner appears to be relying upon KSR International Co. v. Teleflex Inc., in which the Supreme Court stated that a person of ordinary skill in the art (POSA) has good reason to pursue the known options within his or her technical grasp “[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions . . . .” 127 S. Ct. 1727, 1742 (2007). However, the Federal Circuit (Ortho-McNeil Pharma. v. Mylan Labs, Fed. Cir., March 31, 2008, slip op. at 9-10) has recently interpreted “a finite number of identified, predictable solutions” to mean “a finite, and in the context of the art, small or easily traversed, number of options”, where subject matter outside that small, easily traversed number of options does not “support an inference of obviousness”.

Here, there are many different unpredictable variables that the POSA would face in determining the particular electrical waveform to apply to the pelvic muscle of a patient for the purpose of treating a condition of the patient. For the electrical waveform, the variables include, for example, the current, the voltage, the pulse width, the frequency of the pulses, etc. (paragraphs [0172]-[0179] of the present application – U.S. Pub. No. 20050261746). Therefore, the subject matter is far from “small or easily traversed”. As a result, a POSA would not be motivated to explore the copious options for the stimulation signal to ultimately lead to the electrical waveform described in the claims of the present application. Accordingly, the subject matter of at least claims 243, 244, 260, 261, 262, 271 and 272 is non-obvious in view of the cited references.

With regard to independent claim 254, neither Suda et al. nor Barreras disclose “implanting at least one electrode in a patient in a pelvic muscle of the patient selected from the list consisting of a levator ani muscle, and a urethral sphincter muscle”, as provided in claim 254. For at least this reason, claim 254 and its dependent claims, are non-obvious in view of the cited references.

With regard to independent claim 269, neither Suda et al. nor Barreras disclose “driving the at least one electrode using the stimulator device to apply an electrical waveform to the muscle configured to treat a bladder condition caused by damage to nerve pathways from a brain to a bladder”, as recited in claim 269. For at least this reason, claim 269 and its dependent claims, are non-obvious in view of the cited references.

In light of the above arguments, as well as others not presented herein, Applicant reserves the right to pursue embodiments of the invention having a scope that is the same or broader than those presented during the prosecution of the present application in a divisional or continuation application.

### Conclusion

In view of the above-remarks, Applicant believes that the application, as amended, is in condition for allowance. Entry of the amendments and allowance of the application is respectfully requested.

The Director is authorized to charge any fee deficiency required by this paper or credit any overpayment to Deposit Account No. 23-1123.

Respectfully submitted,

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